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STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	10569583
Filing Date	2006-02-23
First Named Inventor	Neil Gallagher
Art Unit	1654
Examiner Name	Julie Ha
Attorney Docket Number	101213-1P US

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1	5464853			1995-11-07	Chan, Ming F. et al.	
2	5514691			1996-05-07	Chan, Ming F. et al.	
3	5843902			1998-12-01	Gamick, Marc B. et al.	
4	5763429			1998-06-09	Bishop, Charles W. et al.	
5	4100274			1978-07-11	Dutta, Anand Swaroop, et al.	
6	4767628			1968-06-30	Hutchinson, Francis G.	

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1	20020055457	A1	2002-05-09	Janus, Todd J. et al.	
2	20050014769	A1	2005-01-20	Osswald, Mathias et al.	
3	20030092757	A1	2003-05-15	Singh, Amitabh et al.	

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FOREIGN PATENT DOCUMENTS

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1	0682016		EP	A1	1995-11-15	Zeneca Ltd.		<input type="checkbox"/>
2	0749964		EP	A1	1996-12-27	Zeneca Ltd.		<input type="checkbox"/>
3	0510526		EP	A1	1992-10-28	F. Hoffmann-La Roche & Co.		<input checked="" type="checkbox"/>
4	0526708		EP	A1	1993-02-10	F. Hoffman-La Roche AG		<input checked="" type="checkbox"/>
5	0558258		EP	A1	1993-09-01	E.R. Squibb & Sons, Inc.		<input type="checkbox"/>
6	0569193		EP	A1	1993-11-10	E.R. Squibb & Sons, Inc.		<input type="checkbox"/>

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7	0640596	EP	A1	1995-03-01	Bristol-Myers Squibb Co.	<input type="checkbox"/>
8	1424080	EP	A1	2004-06-02	Takeda Chemical Industries, Ltd.	<input type="checkbox"/>
9	1256344	EP	A1	2002-11-13	Yamanouchi Pharmaceutical Co., Ltd.	<input type="checkbox"/>
10	2295616	GB	A	1996-06-05	Zeneca Ltd.	<input type="checkbox"/>
11	1995/26957	WO	A1	1995-10-12	Zeneca Ltd.	<input type="checkbox"/>
12	1996/40681	WO	A1	1996-12-19	Zeneca Ltd.	<input type="checkbox"/>
13	1998/40332	WO	A1	1998-09-17	Zeneca Ltd.	<input type="checkbox"/>
14	2004/018044	WO	A2	2004-03-04	AstraZeneca AB	<input type="checkbox"/>
15	2004/032922	WO	A1	2004-04-22	AstraZeneca AB	<input type="checkbox"/>
16	2004/035057	WO	A1	2004-04-29	AstraZeneca AB	<input type="checkbox"/>
17	2005/080403	WO	A2	2005-09-01	AstraZeneca AB	<input type="checkbox"/>

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18	2006/056760	WO	A1	2006-06-01	AstraZeneca AB		<input type="checkbox"/>
19	2001/00198	WO	A2	2001-01-04	California Institute of Technology		<input type="checkbox"/>
20	2000/67024	WO	A1	2000-11-09	New York University		<input type="checkbox"/>
21	2001/60370	WO	A1	2001-08-23	Yamanouchi Pharmaceutical Co. Ltd.		<input checked="" type="checkbox"/>
22	1999/56761	WO	A1	1999-11-11	Davar, Gudarz		<input type="checkbox"/>
23	2002/11713	WO	A2	2002-02-14	Abbott Laboratories		<input type="checkbox"/>
24	2000/36918	WO	A1	2000-06-29	Marine Polymers Technologies, Inc.		<input type="checkbox"/>
25	2002/085351	WO	A1	2002-10-31	Abbott Laboratories		<input type="checkbox"/>
26	2002/49630	WO	A2	2002-06-27	Bristol-Myers Squibb Company		<input type="checkbox"/>
27	1994/27979	WO	A1	1994-12-08	Immunopharmaceutics Inc.		<input type="checkbox"/>
28	200191736	WO	A2	2001-12-06	Warner-Lambert Company		<input type="checkbox"/>

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29	2001/44238	WO	A2	2001-06-21	Bristol-Myers Squibb Company	<input type="checkbox"/>
30	2003/045434	WO	A2	2003-06-05	Board of Trustees of the University of Illinois	<input type="checkbox"/>
31	2003/006041	WO	A1	2003-01-23	Takeda Chemical Industries, Ltd.	<input checked="" type="checkbox"/>
32	2003/015820	WO	A1	2003-02-27	Takeda Chemical Industries, Ltd.	<input checked="" type="checkbox"/>
33	1999/48530	WO	A1	1999-09-30	Merck & Co., Inc.	<input type="checkbox"/>
34	2002/074034	WO	A2	2002-09-26	Boehringer Ingelheim Pharma KG	<input checked="" type="checkbox"/>
35	2002/080960	WO	A2	2002-10-17	Medical Research Council	<input type="checkbox"/>
36	2002/069906	WO	A2	2002-09-12	Cellegy Pharmaceuticals, Inc.	<input type="checkbox"/>
37	2003/009805	WO	A2	2003-02-06	Brigham and Women's Hospital, Inc.	<input type="checkbox"/>
38	2000/21509	WO	A2	2000-04-20	Imperial College Innovations Ltd.	<input type="checkbox"/>
39	1996/09818	WO	A1	1996-04-04	Merck & Co., Inc.	<input type="checkbox"/>

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	40	2003/039539	WO	A2	2003-05-15	Merck Patent GMBH		<input checked="" type="checkbox"/>
	41	2005/063735	WO	A1	2005-07-14	Merck Patent GMBH		<input checked="" type="checkbox"/>
	42	0058481	EP	A1	1982-08-25	Imperial Chemical Industries PLC		<input type="checkbox"/>

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NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T5
	1	MORRIS MICHAEL J ET AL: "Clinical approaches to osseous metastases in prostate cancer." <i>The Oncologist</i> , 2003, pages 161-173, vol. 8, no. 2	<input type="checkbox"/>
	2	ROSANO LAURA A ET AL: "Therapeutic targeting of the endothelin A receptor in human ovarian carcinoma." <i>Cancer Research</i> , 15 May 2003 (2003-05-15), pages 2447-2453, vol. 63, no. 10, XP002365689	<input type="checkbox"/>
	3	WALCZAK J R ET AL: "Pharmacological Treatments for Prostate Cancer," <i>Expert Opinion on Investigational Drugs</i> , 2002, pages 1737-1748, Vol. 11, no. 12, Ashley Publications, Ltd., London, GB, XP009008862	<input type="checkbox"/>
	4	ROSANO, LAURA ET AL, "ZD4054, a specific antagonist of the endothelin A receptor, inhibits tumor growth and enhances cytotoxicity of paclitaxel in human ovarian carcinoma in vitro and in vivo," April 16-20, 2005, AACR, Anaheim/Orange County, CA	<input type="checkbox"/>
	5	CURTIS, N. ET AL: "ZD4054 specifically inhibits endothelin A receptor-mediated anti-apoptotic effects, but not endothelin B receptor-mediated pro-apoptotic effects," September 28-October 1, 2004, AACR-NCI-EORTC, Geneva, Switzerland	<input type="checkbox"/>
	6	LIU, GLENN ET AL, "Tolerability profile of ZD4054 is consistent with the effects of endothelin A receptor-specific antagonism," May 13-17, 2005, ASCO Annual Meeting, Orlando, Florida	<input type="checkbox"/>

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7	MORRIS, C. ET AL., "ZD4054: specificity for endothelin A receptor following single-dose administration in healthy volunteers," September 28-October 1, 2004, AACR-NCI-EORTC, Geneva, Switzerland	<input type="checkbox"/>
8	DREICER, R. ET AL., "ZD4054 specifically inhibits endothelin A receptor-mediated effects but not endothelin B receptor-mediated effects," February 17-19, 2005, ASCO Prostate Cancer Symposium, Orlando, Florida	<input type="checkbox"/>
9	TODD, MARTIN ET AL., "Metabolite Factories: Use of microbial systems to generate metabolites of an endothelin receptor antagonist," July 3-8, 2005, Biotrans 2005, Delft, The Netherlands	<input type="checkbox"/>
10	MORRIS, CD ET AL., "Specific inhibition of the endothelin A receptor with ZD4054: clinical and preclinical evidence," British Journal of Cancer, 2005, 92, 2148-2152	<input type="checkbox"/>
11	CURWEN, J.O., "ZD4054 : a specific endothelin A receptor antagonist with potential utility in prostate cancer and metastatic bone disease," European Journal of Cancer, November 2002 (2002-11), vol. 38, page S102, Pergamon Press, Oxford, GB, XP004403782	<input type="checkbox"/>
12	CURTIS, N. ET AL., "ZD4054 blocks ET-1-stimulated phosphorylation of p44/42 mitogen-activated protein kinase and proliferation of osteoblast cells," April 16-20, 2005, AACR, Anaheim/Orange County, CA	<input type="checkbox"/>
13	MORRIS, C.D. ET AL., "ZD4054 reduces endothelin-1-induced forearm vasoconstriction in healthy male volunteers," April 16-20, 2005, AACR, Anaheim/Orange County, CA	<input type="checkbox"/>
14	ROSANO, LAURA, "Combined targeting of the endothelin receptor and the epidermal growth factor receptor in ovarian cancer shows enhanced antiproliferative effects," April 1-5, 2006, AACR 2006, Washington, DC	<input type="checkbox"/>
15	CURWEN, J. ET AL., "ZD4054 : a specific endothelin A receptor antagonist with potential utility in prostate cancer and metastatic bone disease," 19-22 November 2002, EORTC-NCI-AACR, Frankfurt, Germany	<input type="checkbox"/>
16	NELSON, JOEL B. ET AL., "Endothelin-1 Production and Decreased Endothelin B Receptor Expression in Advanced Prostate Cancer, Journal of Cancer Research, February 15, 1996, pages 663-668, Volume 56	<input type="checkbox"/>
17	KROODSMA, J.M., ET AL., "Endothelinen: modelijk een nieuw farmacologisch aangrijppingspunt bij hartvaatziekten, nierziekten en oncologische aandoeningen." Nederlands Tijdschrift Voor Geneeskunde, 1997, pages 1806-1810, Volume 141, Part 38	<input checked="" type="checkbox"/>

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18	"Endothelin Inhibitors: Exploring Novel Therapeutics.", Symposium, June 7-8, 1999, Washington, DC, Iddb Meeting Report, 25 June 1999	<input type="checkbox"/>
19	BOVEN, E., "American Society of Clinical Oncology-35th Annual Meeting (Part 1), Symposium, May 15-18, 1999, Atlanta, GA, Iddb Meeting Report, 13 September 2001	<input type="checkbox"/>
20	MCKINNON, C., "American Society of Clinical Oncology-35th Annual Meeting (Part 4), Symposium, May 15-18, 1999, Atlanta, GA, Iddb Meeting Report, 13 September 2001	<input type="checkbox"/>
21	ADENIYI, A., "American Urological Association-94th Annual Meeting," Symposium, May 1-6, 1999, Dallas, TX, Iddb Meeting Report, 26 August 1999	<input type="checkbox"/>
22	BOVEN, E., "American Society of Clinical Oncology-35th Annual Meeting, 15-18 May 1999, Atlanta, GA," ID Drugs, 1999, pages 617-619, Vol. 2, No. 7	<input type="checkbox"/>
23	MCKINNON, C., "Topoisomerase inhibitors and other new agents." ID Drugs, 1999, pages 629-632, Vol. 2, No. 7	<input type="checkbox"/>
24	ADENIYI, A., "American Urological Association-94th Annual Meeting May 1-6, 1999, Dallas, TX", ID Drugs, 1999, pages 656-658 Vol. 2, No. 7	<input type="checkbox"/>
25	NELSON, JOEL B., "Editorial: Endothelin Receptor Antagonists in the Treatment of Prostate Cancer," The Prostate, pages 91-92, 2001, Volume 49	<input type="checkbox"/>
26	NELSON, JOEL B., "The Role of the Endothelin Axis in Prostate Cancer," The Prostate Journal, pages 126-130, 1999, Volume 1, Number 3	<input type="checkbox"/>
27	NELSON, JOEL B., "The Role of Endothelin-1 and Endothelin Receptor Antagonists in Prostate Cancer, British Journal of Urology, pages, 45-48, 2000, Volume 85, Suppl. 2	<input type="checkbox"/>
28	NELSON, JOEL B., "Identification of endothelin-1 in the pathophysiology of metastatic adenocarcinoma of the prostate", Nature Medicine, pages 944-949, September 1995, Volume 1, No. 9	<input type="checkbox"/>

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29	CARLUCCI, MICHAEL A., "Endothelin Receptor Antagonist, ABT-627, For Prostate Cancer Initial Trial Results," The Journal of Urology, page 176, 1999, Volume 161(4) Suppl	<input type="checkbox"/>
30	JARVIS, MICHAEL F., ET AL., "ABT-627, an endothelin ETA receptor-selective antagonist, attenuates tactile allodynia in a diabetic rat model of neuropathic pain," European Journal of Pharmacology, pages 29-35, 2000, Vol. 388, No. 1	<input type="checkbox"/>
31	WILLIAMS, E.D., "The combination of a specific endothelin A receptor antagonist ZD4054 and submaximal bisphosphonate pamidronate prevents bone metastasis," Poster Session, Angiogenesis and metastasis inhibitors, 8 November 2006, European Journal of Cancer Supplements, page 15, Volume 4, No. 12, page 15.	<input type="checkbox"/>
32	BAGNATO, ANNA, ET AL., "Autocrine Actions of Endothelin-1 as a Growth Factor in Human Ovarian Carcinoma Cells," Clinical Cancer Research, 1995, pages 1059-1066, Vol. 1.	<input type="checkbox"/>
33	WU-WONG, JINSHYUN R., "Endothelin attenuates apoptosis in human smooth muscle cells," Biochemical Journal, pages 733-737, 1997, Vol. 328	<input type="checkbox"/>
34	SPINELLA, FRANCESCA, ET AL., "Endothelin-1 Induces Vascular Endothelial Growth Factor by Increasing Hypoxia-inducible Factor-1α in Ovarian Carcinoma Cells," The Journal of Biological Chemistry, pages 27850-27855, August 2, 2002, Volume 277, No. 31	<input type="checkbox"/>

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EXAMINER SIGNATURE

Examiner Signature	Date Considered
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CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

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See attached certification statement.

Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Lucy Padget/	Date (YYYY-MM-DD)	2007-01-19
Name/Print	Lucy Padget	Registration Number	L0074

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